IN THE UNITED STATES DISTRICT COURT

District of Minnesota

Gladys Mensing,	CASE NO. 07cv3919 PJS/RLE
v.	
WYETH, INC. (d/b/a WYETH); SCHWARZ PHARMA, INC.; PLIVA, INC.; TEVA PHARMACEUTICALS, USA, INC.; ALPHARMA, INC., d/b/a ALPHARMA PHARMACEUTICALS; UDL LABORATORIES, INC.; ACTAVIS ELIZABETH, LLC, and PUREPAC PHARMACEUTICAL CO., and the following fictitious party defendants (whether singular or plural, individual or corporate): No. 1, that entity which originally obtained permission from the U.S. Food and Drug Administration to market the drug branded Reglan; No. 2, that entity which obtained permission from the FDA to market the Reglan, metoclopramide and/or metoclopramide HCl ingested by Gladys Mensing; No. 3, that entity which originally manufactured and sold any Reglan which was ultimately ingested by Gladys Mensing; No. 4, that entity which originally manufactured and sold any Reglan, metoclopramide and/or metoclopramide HCl which was ultimately ingested by Gladys Mensing; No. 5, that entity which marketed Reglan or generic metoclopramide and/or metoclopramide HCl.	**COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**
Defendants.	

Gladys Mensing, Plaintiff, by and through her undersigned attorneys, state and allege as follows:

I. PARTIES

1. Gladys Mensing, Plaintiff, (hereinafter referred to as "Plaintiff") is an individual of the full age of majority who is a resident and citizen of Steele County, State of Minnesota.

2. Plaintiff brings this action for the purpose of recovering all damages allowable by law for personal injuries she suffered as a result the ingestion of Reglan, metoclopramide and/or metoclopramide HCl.

3. Defendant, Wyeth, Inc., d/b/a Wyeth (hereinafter "Wyeth") is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey 07940.

4. References in this Complaint to "Wyeth" include individually and collectively all divisions and/or subsidiaries, Wyeth as successor in interest to A.H. ROBINS, INC., AMERICAN HOME Drugs CORPORATION, and ESI.

5. At all times material hereto, Wyeth was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan, metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and in interstate commerce. Wyeth may be served with process through its registered agent, Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808. Wyeth is subject to the jurisdiction and venue of this Court.

6. Wyeth manufactures and distributes generic metoclopramide through its ownership of ESI Ledule, Inc. (a former subsidiary which merged into Wyeth).

7. Defendant, Schwarz Pharma, Inc., (hereinafter "Schwarz") is a Delaware corporation, duly qualified to do business in the State of Minnesota with its principal place of business in Mequon, Wisconsin.

8. Defendant Schwarz and/or one of its predecessors in interest and/or one of its family of wholly owned divisions was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest, or other related entities, Reglan, metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and

in interstate commerce. Schwarz may be served with process through its registered agent, CSC Entity Services, LLC, 103 Foulk Road, Suite 200, Wilmington, Delaware 19803. Schwarz Pharma, Inc. is subject to the jurisdiction and venue of this Court.

9. The Defendant, PLIVA USA, Inc., (hereinafter "PLIVA") is a New York corporation with its principal place of business in New Jersey.

10. At all times material hereto, PLIVA was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan, metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and in interstate commerce. PLIVA may be served with process through its agent for service of process at Corporation Trust Company, 820 Bear Tavern Road, 3rd Floor, West Trenton, NJ 08628. PLIVA is subject to the jurisdiction and venue of this Court.

11. The Defendant, Teva Pharmaceuticals, USA, Inc., (hereinafter "Teva") is a Delaware corporation with its principal place of business in Pennsylvania. At all times material hereto, Teva was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan, metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and in interstate commerce. Teva may be served with process through its registered agent, the Corporation Trust Company, located at Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Teva is subject to the jurisdiction and venue of this Court.

12. The Defendant, Alpharma Inc., d/b/a Alpharma Pharmaceuticals (hereinafter "Alpharma"), is a Delaware Corporation and is the parent corporation of Purepac Pharmaceutical Co., which at all times pertinent hereto manufactured and distributed the generic drug metoclopramide and/or metoclopramide HCl.

13. At all times material hereto, Alpharma was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan, metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and in interstate commerce. Alpharma is subject to the jurisdiction and venue of this Court. Alpharma may be served with process through its agent for service: Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19809.

14. The Defendant, Purepac Pharmaceutical Co. (hereinafter "Purepac"), is a New Jersey Corporation. At all times material hereto, Purepac was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan, metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and in interstate commerce. Purepac may be served with process through its corporate headquarters, 1 Executive Drive, Fort Lee, New Jersey 07024-3309. Purepac is subject to the jurisdiction and venue of this Court.

15. The Defendant, UDL Laboratories, Inc., is an Illinois Corporation. At all times material hereto, UDL was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan, metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and in interstate commerce. UDL Laboratories, Inc., may be served with process through its agent for process: Illinois Corporation Service, 801 ADLAI Stevenson Drive, Springfield, Illinois 62703. UDL Laboratories, Inc., is subject to the jurisdiction and venue of this Court.

16. The Defendant, Actavis Elizabeth, LLC, (hereinafter "Actavis"), is a New Jersey Corporation. At all times material hereto, Actavis was engaged in the business of testing,

developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities, Reglan/metoclopramide and/or metoclopramide HCl tablets in the State of Minnesota and in interstate commerce. Actavis is subject to the jurisdiction and venue of this Court.

17. Fictitious parties No. 1 through 6 are party Defendants the identities of whom or which is otherwise known to Plaintiff at this time, but, whose true names will be substituted by amendment when the aforesaid lacking knowledge is ascertained.

18. All Defendants, identified *supra*, inclusive, and each of them, may be referred to in this complaint collectively as "THE DRUG COMPANY DEFENDANTS."

19. At all relevant times, DRUG COMPANY DEFENDANTS were acting by and through their agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

20. At all times relevant hereto, DRUG COMPANY DEFENDANTS were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising the pharmaceutical drugs known as "Reglan", metoclopramide HCl and/or metoclopramide in the State of Minnesota and in interstate commerce.

21. At all relevant times, DRUG COMPANY DEFENDANTS did manufacture, create, design, assemble, test, label, sterilize, package, distribute, promote, supply, market, sell, advertise, and/or otherwise distribute in the State of Minnesota and in interstate commerce Reglan and/or metoclopramide tablets.

22. At all relevant times, DRUG COMPANY DEFENDANTS sold, delivered and/or distributed such drugs for ultimate sale and/or use interstate commerce within the United States and the State of Minnesota by foreseeable users, including Plaintiff.

II. VENUE AND JURISDICTION

23. The venue of this action is proper because Plaintiff is a resident of the State of Minnesota and the acts of negligence occurred in the State of Minnesota.

24. DRUG COMPANY DEFENDANTS conducted business in the State of Minnesota through pharmaceutical sales representatives conducting business in the State of Minnesota on behalf of Defendants and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties or related entities tablets known as Reglan, metoclopramide HCL and/or metoclopramide; thus, there exists a sufficient nexus between the DRUG COMPANY DEFENDANTS' forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Minnesota.

III. FACTUAL BACKGROUND OF PLAINTIFF'S CLAIMS

25. During all material times, Gladys Mensing, (hereinafter referred to as "Plaintiff") was domiciled in the State of Minnesota.

26. On or about March 23, 2001, Plaintiff's physician prescribed Reglan at a dosage of 5 mg, b.i.d., to treat Plaintiff's diabetic gastroparesis.

27. The active ingredient, metoclopramide and metoclopramide HCl is a dopamine antagonist.

28. Subsequently, Plaintiff's physician increased Plaintiff's dosage to 10 mg to be taken four (4) times a day.

29. Subsequently, Plaintiff's physician increased the dosage of Plaintiff's prescription for Reglan, metoclopramide, and/or metoclopramide HCl, and prescribed it to Plaintiff for several years thereafter.

30. Upon information and belief, in prescribing the Reglan, metoclopramide, and/or metoclopramide HCl drugs to Plaintiff on a long-term basis, Plaintiff's physicians relied upon information published in the package inserts and/or the Physician's Desk Reference

(hereinafter "PDR") or otherwise disseminated by the Reference Listed Drug Company (hereinafter "RLD") and/or the New Drug Application Holder (hereinafter "NDA holder"), in particular, that information disseminated by Defendants Wyeth and Schwarz.

31. Plaintiff ingested Reglan, metoclopramide and/or metoclopramide HCl, as prescribed.

32. Plaintiff's long term ingestion of Reglan, metoclopramide and/or metoclopramide HCl caused her injuries.

33. Plaintiff's physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR.

34. Wyeth and Schwarz, as the RLD and/or NDA holders, provided misleading information about the true risks associated with the use of Reglan, metoclopramide, and/or metoclopramide HCl to the medical community, Plaintiff's Physician, and Plaintiff (and other foreseeable users similarly situated).

35. On or about March of 2005, Plaintiff was taken to Plaintiff's physician, who discontinued Plaintiff's Reglan, metoclopramide, and/or metoclopramide HCl prescription due to the clinical presentation of lip smacking and tongue thrusting movements.

36. On or about September of 2005, Plaintiff was examined by Dr. Bruce A. Evans, Department of Neurology, Mayo Clinic, who diagnosed her as suffering from drug induced Tardive Dyskinesia related to her long-term use of Reglan, metoclopramide, and/or metoclopramide HCl.

37. Plaintiff used the pharmaceutical drugs Reglan, metoclopramide, and/or metoclopramide HCl without substantial change in condition of the drugs between the time of design and manufacture of the drugs and the time Plaintiff used the drugs as directed.

38. Plaintiff's use of Reglan, metoclopramide, and/or metoclopramide HCl drugs, as prescribed, resulted in overexposure to the drugs Reglan, metoclopramide, and/or

metoclopramide HCl which caused Plaintiff to suffer serious, permanent and disabling injuries, including but not limited to injuries of or associated with the central nervous and extrapyramidal motor systems, specifically Tardive Dyskinesia, a severe and often permanent disfiguring neurological movement disorder.

39. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of the RLD and/or NDA holder and the ANDA holders dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Reglan, metoclopramide, and/or metoclopramide HCl and the ingestion of Reglan, metoclopramide, and/or metoclopramide HCl drug to the medical community, physicians, Plaintiff's physician, Plaintiff and other foreseeable users of the drug.

40. Use of Reglan, metoclopramide, and/or metoclopramide HCl caused Plaintiff to suffer serious, permanent and disabling injuries including but not limited to injuries of or associated with the central nervous and extrapyramidal motor systems.

41. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries she suffered caused by the ingestion of this drug.

IV. ALLEGATIONS

42. Tardive dyskinesia is a debilitating neurological disorder that often results in involuntary and uncontrollable movements of the head, neck, face, arms, legs and trunk in addition to grotesque facial grimacing and open-mouthed, uncontrollable tongue movements, tongue thrusting, tongue chewing, and other involuntary movements.

43. Presently, there is no cure for tardive dyskinesia.

44. Plaintiff's condition is permanent.

45. Wyeth is the successor in interest to A.H. Robins Company, Inc., a Virginia corporation which first obtained approval by the United States Food and Drug Administration (hereinafter "FDA") to distribute metoclopramide, under the brand name "Reglan" under the FDA's New Drug Application (NDA)[1] schema.

46. Under the FDA schema, Wyeth was/is the Reference Listed Drug Company (RLD), under a specific NDA, for Reglan, metoclopramide and metoclopramide HCl.

47. Wyeth knew that it must fully, truthfully and accurately disclose and communicate material safety data and information regarding a new drug's chemistry, proposed manufacturing process, proposed model labeling which includes warnings about risks and side effects, test results for the drug, results of animal studies, results of clinical studies and the drug's bioavailability, because the data and information would be relied upon by the medical community, physicians, Plaintiff's physician, Plaintiff and other like foreseeable users of Reglan, metoclopramide and metoclopramide HCl once the NDA was approved and Wyeth was listed as the Reference Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl.

48. Wyeth failed to fully, truthfully and accurately communicate the risks of Reglan, metoclopramide and metoclopramide HCl, and as a result intentionally and fraudulently mislead the medical community, physicians, Plaintiff's physician and Plaintiff about the risks associated with long term use of metoclopramide.

49. Wyeth had a duty to ensure its warnings to the medical community are accurate and adequate; has a duty to conduct safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

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[1]Upon information and belief, Plaintiff believes Wyeth to be the holder of multiple NDAs' for Reglan, metoclopramide and metoclopramide HCl.

50. Wyeth knowingly, intentionally and negligently disseminated misleading information to physicians' across the country, through a publication known as the *Physicians' Desk Reference*, labeling information for Reglan, metoclopramide and metoclopramide HCl which mislead the medical community, physicians and Plaintiff's physician about the risks of long term ingestion of the drug.

51. Wyeth knowingly, intentionally and negligently disseminated misleading information to physicians' across the country, through a publication known as the *Physicians' Desk Reference*, labeling information for Reglan, metoclopramide and metoclopramide HCl which mislead the medical community, physicians and Plaintiff's physician about the increased risk of extrapyramidal side effects, including tardive dyskinesia, diabetics, including Plaintiff, were exposed to.

52. Wyeth manufactured, marketed and distributed Reglan, metoclopramide, and/or metoclopramide HCl through its Wyeth-Ayerst Laboratories Division in St. Davids, Pennsylvania.

53. At all times relevant herein, Wyeth manufactured, marketed and distributed *generic* (also known as "branded generic") Reglan, metoclopramide, and/or metoclopramide HCl through its ownership of ESI LEDERLE, INC. (hereinafter "ESI").[2]

54. Wyeth manufactures and distributes Reglan, branded generic and/or generic metoclopramide and/or metoclopramide HCl through its ownership of ESI Lederle.

55. Defendant Schwarz purchased from Wyeth the rights and *liabilities* associated with Reglan, metoclopramide and metoclopramide HCl tablets, upon information and belief, the terms of which obligated Schwarz to be responsible for claims related to the ingestion

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[2]Upon information and belief, ESI was a former subsidiary which merged into Wyeth on or about December 15, 1998.

or use of Reglan, metoclopramide and metoclopramide HCl, subject to a right of indemnification from Wyeth up to a certain dollar amount.[3]

56. Defendant Schwarz was/and remains the RLD and/or NDA holder, for Reglan, metoclopramide and metoclopramide HCl tablets.

57. Wyeth reviewed the article published in the *Archives of Internal Medicine*, in 1989, and written by Joseph Jankovic, entitled "Metoclopramide-Induced Movement Disorders: A Review of the Literature."

58. Wyeth reviewed the article published in the *Annals of Pharmacology*, in 1992, written by Dr. Ronald Stewart, entitled "An Analysis of Inappropriate Long-Term Use in the Elderly."

59. Wyeth reviewed the epidemiological study published in the medical literature, specifically the *Archives of Internal Medicine,* in June of 1993, and written by Linda Ganzini.

60. Wyeth reviewed the epidemiological study published and written by Dr. Daniel Sewell in 1994, regarding the frequency of tardive dyskinesia in metoclopramide treated patients.

61. Wyeth reviewed the medical literature written by authors, Yassa & Jeste, in 1992, regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

62. Schwarz reviewed the article published in the *Archives of Internal Medicine*, in 1989, and written by Joseph Jankovic, entitled "Metoclopramide-Induced Movement Disorders: A Review of the Literature."

63. Schwarz reviewed the article published in the *Annals of Pharmacology*, in 1992, written by Dr. Ronald Stewart, entitled "An Analysis of Inappropriate Long-Term Use in the Elderly."

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[3]Plaintiff does not have information regarding the maximum amount of liability under the defendants' indemnification agreement.

64. Schwarz reviewed the epidemiological study published in the medical literature, specifically the *Archives of Internal Medicine,* in June of 1993, and written by Linda Ganzini.

65. Schwarz reviewed the epidemiological study published and written by Dr. Daniel Sewell in 1994, regarding the frequency of tardive dyskinesia in metoclopramide treated patients.

66. Schwarz reviewed the medical literature written by authors, Yassa & Jeste, in 1992, regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

67. Schwarz had a duty to ensure its warnings to the medical community are accurate and adequate; had a duty to conduct safety surveillance of adverse events for the drug, and to report *any* data related to the safety and/or accuracy of the warnings and information disseminated regarding the drug.

68. Schwarz manufactured, marketed and distributed Reglan, metoclopramide and/or metoclopramide HCl at all relevant material times herein.

69. Wyeth breached its duty to the medical community, Plaintiff's physicians, Plaintiff and other foreseeable users similarly situated, in that it failed to ensure Reglan, metoclopramide and metoclopramide HCl warnings to the medical community, physicians, Plaintiff's physician and Plaintiff were accurate and adequate.

70. Wyeth breached its joint duty to the medical community, to Plaintiff's physicians, Plaintiff, and other foreseeable users similarly situated, in that it failed to conduct post market safety surveillance and report that information the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

71. Wyeth breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated, because it failed to review all adverse drug

event information (ADE),[4] and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

72. Wyeth breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated, in that it failed to periodically review all medical literature regarding Reglan, metoclopramide, and metoclopramide HCl, and failed to report data, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide and metoclopramide HCl.

73. Schwarz breached its duty to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users similarly situated, because it failed to ensure Reglan, metoclopramide, and metoclopramide HCl warnings to the medical community were accurate and adequate.

74. Schwarz breached its duty to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users similarly situated, because it failed to conduct post market safety surveillance and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

75. Schwarz breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan,

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[4]*See* 21 C.F.R. § 317.80(b).

metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

76. Schwarz breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

77. Defendant PLIVA submitted an Abbreviated New Drug Application to the U.S. Food and Drug Administration, based on representations made by the RLD Company, requesting permission to manufacture, market, and distribute metoclopramide and/or metoclopramide HCl.

78. Under the ANDA process, the Code of Federal Regulations *required* Defendant PLIVA to submit a label for metoclopramide and metoclopramide HCl, initially identical in all material aspects to the reference listed drug label.

79. Defendant PLIVA began selling generic metoclopramide and/or metoclopramide HCl in 1988.

80. PLIVA did not investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug label.

81. PLIVA did not review the medical literature for the metoclopramide drug.

82. PLIVA did not review the medical literature for the metoclopramide and/or metoclopramide HCl drug.

83. PLIVA is under a duty to ensure that its metoclopramide label is accurate.

84. PLIVA did not review the article published in the *Archives of Internal Medicine*, in 1989, and written by Joseph Jankovic, entitled "Metoclopramide-Induced Movement Disorders:

A Review of the Literature."

85. PLIVA did not review the article published in the *Annals of Pharmacology*, in 1992, written by Dr. Ronald Stewart, entitled "An Analysis of Inappropriate Long-Term Use in the Elderly."

86. PLIVA did not review the epidemiological study published in the medical literature, specifically the *Archives of Internal Medicine,* in June of 1993, and written by Linda Ganzini.

87. PLIVA did not review the epidemiological study published and written by Dr. Daniel Sewell in 1994, regarding the frequency of tardive dyskinesia in metoclopramide treated patients.

88. PLIVA did not review the medical literature written by authors, Yassa & Jeste, in 1992, regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

89. PLIVA relied upon the name brand manufacturer to review the aforementioned medical literature for the metoclopramide drug.

90. PLIVA relied upon the reference listed drug company for the reference listed metoclopramide drug to review the aforementioned medical literature.

91. Under the Code of Federal Regulations, Defendant PLIVA, as an ANDA holder, had a duty to ensure its Reglan, metoclopramide, and metoclopramide HCl warnings to the medical community were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other foreseeable users.

92. Under the Code of Federal Regulations, if Defendant PLIVA, as the ANDA holder, discovers information in the course of the fulfillment of its duties as outlined above, Defendant PLIVA must report that information to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users of Reglan, metoclopramide and metoclopramide HCl to ensure that its warnings are continually accurate and adequate.

93. PLIVA breached its duty to the medical community, Plaintiff's Physician, Plaintiff, and other foreseeable users similarly situated because it failed to ensure Reglan, metoclopramide, and/or metoclopramide HCl warnings to the medical community, Plaintiff's physician, Plaintiff, other foreseeable users similarly situated were accurate and adequate.

94. PLIVA breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

95. PLIVA breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

96. PLIVA breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy

of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

97. PLIVA breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to communicate the true and accurate risks and/or prevalence of severe neurological side effects resulting from the ingestion of drugs containing the active ingredient metoclopramide and/or metoclopramide HCl.

98. Defendant TEVA submitted an Abbreviated New Drug Application to the U.S. Food and Drug Administration, based on representations made by the RLD Company, requesting permission to manufacture, market, and distribute metoclopramide and/or metoclopramide HCl.

99. Under the ANDA process, the Code of Federal Regulations *required* Defendant Teva to submit a label for metoclopramide and metoclopramide HCl, initially identical in all material aspects as to the reference listed drug label.

100. Teva did not investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug label.

101. Teva did not review the medical literature for the metoclopramide and/or metoclopramide HCl drug.

102. Teva is under a duty to ensure that its metoclopramide label is accurate.

103. Teva did not review the article published in the *Archives of Internal Medicine*, in 1989, and written by Joseph Jankovic, entitled "Metoclopramide-Induced Movement Disorders: A Review of the Literature."

104. Teva did not review the article published in the *Annals of Pharmacology*, in 1992, written by Dr. Ronald Stewart, entitled "An Analysis of Inappropriate Long-Term Use in the Elderly."

105. Teva did not review the epidemiological study published in the medical literature, specifically the *Archives of Internal Medicine,* in June of 1993, and written by Linda Ganzini.

106. Teva did not review the epidemiological study published and written by Dr. Daniel Sewell in 1994, regarding the frequency of tardive dyskinesia in metoclopramide treated patients.

107. Teva did not review the medical literature written by authors, Yassa & Jeste, in 1992, regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

108. Teva relied upon the name brand manufacturer to review the aforementioned medical literature for the metoclopramide drug.

109. Teva relied upon the reference listed drug company for the reference listed metoclopramide drug to review the aforementioned medical literature.

110. Under the Code of Federal Regulations, Defendant Teva, as an ANDA holder, had a duty to ensure its warnings to the medical community were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users.

111. Under the Code of Federal Regulations, if Defendant Teva, as the ANDA holder, discovers information in the course of the fulfillment of its duties as outlined above, Defendant Teva, must report that information to ensure that its warnings for Reglan, metoclopramide and metoclopramide HCl are continually accurate and adequate.

112. Teva breached its duty to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users similarly situated because it failed to ensure Reglan, metoclopramide, and/or metoclopramide HCl warnings to the medical community, Plaintiff's physician,

Plaintiff, other foreseeable users similarly situated were accurate and adequate.

113. Teva breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

114. Teva breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated because it failed to and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

115. Teva breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to communicate and report material safety information, as reported in the medical literature, concerning neurological side effects, to the medical community, the Plaintiff's physician, the Plaintiff and other foreseeable users of Reglan/metoclopramide and metoclopramide HCl.

116. Under the ANDA process, the Code of Federal Regulations *required* Defendant UDL Laboratories to submit a label for metoclopramide and metoclopramide HCl, identical in all material aspects as to the reference listed drug label.

117. Under the Code of Federal Regulations, Defendant UDL Laboratories, as an ANDA holder, has a duty to ensure its warnings to the medical community were accurate and adequate; has a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report and communicate any information bearing on the

risk and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users.

118. Under the Code of Federal Regulations, if Defendant UDL Laboratories, as the ANDA holder, discovers information in the course of the fulfillment of its duties as outlined above, Defendant UDL, must report that information to ensure that its warnings for Reglan, metoclopramide and metoclopramide HCl are continually accurate and adequate.

119. UDL did not investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug label.

120. UDL did not review the medical literature for the metoclopramide drug.

121. UDL did not review the medical literature for the metoclopramide and/or metoclopramide HCl drug.

122. UDL is under a duty to ensure that its metoclopramide label is accurate.

123. UDL did not review the article published in the *Archives of Internal Medicine*, in 1989, and written by Joseph Jankovic, entitled "Metoclopramide-Induced Movement Disorders: A Review of the Literature."

124. UDL did not review the article published in the *Annals of Pharmacology*, in 1992, written by Dr. Ronald Stewart, entitled "An Analysis of Inappropriate Long-Term Use in the Elderly."

125. UDL did not review the epidemiological study published in the medical literature, specifically the *Archives of Internal Medicine,* in June of 1993, and written by Linda Ganzini.

126. UDL did not review the epidemiological study published and written by Dr. Daniel Sewell in 1994, regarding the frequency of tardive dyskinesia in metoclopramide treated patients.

127. UDL did not review the medical literature written by authors, Yassa & Jeste, in 1992,

regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

128. UDL relied upon the name brand manufacturer to review the aforementioned medical literature for the metoclopramide drug.

129. UDL relied upon the reference listed drug company for the reference listed metoclopramide drug to review the aforementioned medical literature.

130. UDL Laboratories breached its duty to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users similarly situated because it failed to ensure its warnings regarding Reglan, metoclopramide, and/or metoclopramide HCl to the medical community, Plaintiff's physician, plaintiff and other like foreseeable users, were adequate and accurate.

131. UDL Laboratories breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

132. UDL Laboratories breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

133. UDL Laboratories breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data

concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

134. Defendant ACTAVIS ELIZABETH, LLC submitted an Abbreviated New Drug Application to the U.S. Food and Drug Administration, based on representations made by the RLD Company, requesting permission to manufacture, market, and distribute metoclopramide and/or metoclopramide HCl.

135. Under the ANDA process, the Code of Federal Regulations *required* Defendant ACTAVIS ELIZABETH, LLC to submit a label for metoclopramide and metoclopramide HCl, identical in all material aspects as to the reference listed drug label.

136. Under the Code of Federal Regulations, Defendant ACTAVIS ELIZABETH, LLC, as an ANDA holder, had a duty to ensure its warnings to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users.

137. ACTAVIS ELIZABETH, LLC, did not investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug label.

138. ACTAVIS ELIZABETH, LLC, did not review the medical literature for the metoclopramide drug.

139. ACTAVIS ELIZABETH, LLC, did not review the medical literature for the metoclopramide and/or metoclopramide HCl drug.

140. ACTAVIS ELIZABETH, LLC, is under a duty to ensure that its metoclopramide label is accurate.

141. ACTAVIS ELIZABETH, LLC, did not review the article published in the *Archives of Internal Medicine*, in 1989, and written by Joseph Jankovic, entitled "Metoclopramide-Induced Movement Disorders: A Review of the Literature."

142. ACTAVIS ELIZABETH, LLC, did not review the article published in the *Annals of Pharmacology*, in 1992, written by Dr. Ronald Stewart, entitled "An Analysis of Inappropriate Long-Term Use in the Elderly."

143. ACTAVIS ELIZABETH, LLC, did not review the epidemiological study published in the medical literature, specifically the *Archives of Internal Medicine,* in June of 1993, and written by Linda Ganzini.

144. ACTAVIS ELIZABETH, LLC, did not review the epidemiological study published and written by Dr. Daniel Sewell in 1994, regarding the frequency of tardive dyskinesia in metoclopramide treated patients.

145. ACTAVIS ELIZABETH, LLC, did not review the medical literature written by authors, Yassa & Jeste, in 1992, regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

146. ACTAVIS ELIZABETH, LLC, relied upon the name brand manufacturer to review the aforementioned medical literature for the metoclopramide drug.

147. ACTAVIS ELIZABETH, LLC, relied upon the reference listed drug company for the reference listed metoclopramide drug to review the aforementioned medical literature.

148. Under the Code of Federal Regulations, if Defendant ACTAVIS ELIZABETH, LLC., as the ANDA holder, discovers information in the course of the fulfillment of its duties as outlined above, Defendant ACTAVIS ELIZABETH, LLC must report that information to ensure that its warnings for Reglan, metoclopramide and metoclopramide HCl are continually accurate and adequate.

149. ACTAVIS ELIZABETH, LLC breached its duty to the medical community, Plaintiff's

physician, Plaintiff and other foreseeable users similarly situated because it failed to ensure its warnings regarding Reglan, metoclopramide, and/or metoclopramide HCl to the medical community, Plaintiff's physician, plaintiff and other like foreseeable users, were adequate and accurate.

150. ACTAVIS ELIZABETH, LLC, breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

151. ACTAVIS ELIZABETH, LLC breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

152. ACTAVIS ELIZABETH, LLC., breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

153. Defendant Purepac submitted an Abbreviated New Drug Application to the U.S. Food and Drug Administration, based on representations made by the RLD Company, requesting permission to manufacture, market, and distribute metoclopramide and/or

metoclopramide HCl.

154. Under the ANDA process, the Code of Federal Regulations *required* Defendant Purepac to submit a label for metoclopramide and metoclopramide HCl, identical in all material aspects as to the reference listed drug label.

155. Under the Code of Federal Regulations, Defendant Purepac, as an ANDA holder, had a duty to ensure its warnings to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users.

156. Purepac did not investigate the accuracy of its metoclopramide and/or metoclopramide HCl drug label.

157. Purepac did not review the medical literature for the metoclopramide drug.

158. Purepac did not review the medical literature for the metoclopramide and/or metoclopramide HCl drug.

159. Purepac is under a duty to ensure that its metoclopramide label is accurate.

160. Purepac did not review the article published in the *Archives of Internal Medicine*, in 1989, and written by Joseph Jankovic, entitled "Metoclopramide-Induced Movement Disorders: A Review of the Literature."

161. Purepac did not review the article published in the *Annals of Pharmacology*, in 1992, written by Dr. Ronald Stewart, entitled "An Analysis of Inappropriate Long-Term Use in the Elderly."

162. Purepac did not review the epidemiological study published in the medical literature, specifically the *Archives of Internal Medicine,* in June of 1993, and written by Linda

Ganzini.

163. Purepac did not review the epidemiological study published and written by Dr. Daniel Sewell in 1994, regarding the frequency of tardive dyskinesia in metoclopramide treated patients.

164. Purepac did not review the medical literature written by authors, Yassa & Jeste, in 1992, regarding the prevalence of tardive dyskinesia in patients exposed to long term neuroleptic drugs.

165. Purepac relied upon the name brand manufacturer to review the aforementioned medical literature for the metoclopramide drug.

166. Purepac relied upon the reference listed drug company for the reference listed metoclopramide drug to review the aforementioned medical literature.

167. Under the Code of Federal Regulations, if Defendant Purepac, as the ANDA holder, discovers information in the course of the fulfillment of its duties as outlined above, Defendant Purepac must report that information to ensure that its warnings for Reglan, metoclopramide and metoclopramide HCl are continually accurate and adequate.

168. Purepac breached its duty to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users similarly situated because it failed to ensure its warnings regarding Reglan, metoclopramide, and/or metoclopramide HCl to the medical community, Plaintiff's physician, plaintiff and other like foreseeable users, were adequate and accurate.

169. Purepac breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

170. Purepac breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

171. Purepac breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

172. The generic defendants named herein relied upon the data and information for the reference listed drug at issue in this litigation to evaluate safety and efficacy of their generic metoclopramide and/or metoclopramide HCl drug.

173. The generic defendants label for metoclopramide and/or metoclopramide HCl utilized the same safety, efficacy and warnings regarding extrapyramidal side effects of this drug.

174. If a generic drug company learns of side effects, risks or misleading and inaccurate information in the Reglan, metoclopramide and metoclopramide HCl label, it must request and/or submit labeling revision for the drug.

175. The generic defendants knew or should have known about the side effects, risks, misleading and inaccurate information contained in the Reglan, metoclopramide and metoclopramide HCl and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiff's

physicians and other foreseeable users.

176. Under the FDA schema, if the FDA approves a label change as requested by an ANDA holder, the NDA holder (also referred to as the Reference Listed Drug Company) ***must amend*** its label.

177. The NDA holder and each individual ANDA holder are under a joint duty to ensure its warnings to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users are accurate and adequate for their drug products.

178. The NDA holder and all ANDA holders are under a joint duty to ensure that their drugs, specifically Reglan, metoclopramide and metoclopramide HCl warnings to the medical community, Plaintiff's physician, Plaintiff and foreseeable users alike, are accurate and adequate at all times.

179. Defendant WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle) submitted an Abbreviated New Drug Application to the U.S. Food and Drug Administration, based on representations made by the RLD Company, requesting permission to manufacture, market, and distribute metoclopramide and/or metoclopramide HCl.

180. Under the ANDA process, the Code of Federal Regulations *required* Defendant WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle) to submit a label for metoclopramide and metoclopramide HCl drugs based upon data, information and representations materially identical to the reference listed drug label for that drug.

181. Defendant WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), as an ANDA holder, had a duty to ensure its warnings to the medical community were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug experience information (ADE) and to report any data (medical literature) regarding the adequacy and accuracy of the risk and or prevalence of contracting a severe neurological disorder.

182. Under the Code of Federal Regulations, if Defendant WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), as the ANDA holder, discovers information in the course of the fulfillment of its duties as outlined above, Defendant WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), must report that information to the medical community, Plaintiff's physician, plaintiff and other foreseeable users.

183. WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle) breached its duty to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users similarly situated because it failed to ensure its warnings regarding Reglan, metoclopramide, and/or metoclopramide HCl to the medical community, Plaintiff's physician, plaintiff and other like foreseeable users, were adequate and accurate.

184. WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

185. WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle) breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users similarly situated because it failed to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

186. WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), breached its duty to the medical community, the Plaintiff's physician, the Plaintiff, and other foreseeable users

similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

187. Federal regulations impose a joint duty on the NDA holder and all ANDA holders to conduct post market safety surveillance and to communicate any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide and metoclopramide HCl to the medical community, Plaintiff's physician,Plaintiff, and other foreseeable users of Reglan/metoclopramide and metoclopramide HCl.

188. The NDA holder and all ANDA holders are under a joint duty to review all adverse drug experience information (ADE)[5] and to report any significant date regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide and metoclopramide HCl to the medical community, physicians, Plaintiff's physician, plaintiff and other foreseeable users.

189. The NDA holder and ANDA holders are under a joint duty to periodically review all medical literature and to report any significant data, no matter the degree of significance, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide and metoclopramide HCl to ensure that its labels are continually accurate and adequate.

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[5]Defendants are required to review all adverse drug experience information obtained or otherwise received...from any source..including derived from postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports from the scientific literature, and unpublished scientific reports.

21 C.F.R. § 317.80(b).

190. Wyeth and Schwarz, NDA holders and Teva, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physician, Plaintiff and other foreseeable users alike, in that they failed to ensure Reglan, metoclopramide and metoclopramide HCl warnings to the medical community, including Plaintiff's physician and/or Plaintiff, were accurate and adequate.

191. Wyeth and Schwarz, NDA holders and Defendant Teva, ANDA holder, jointly breached their joint duty to the medical community, including Plaintiff's physicians, Plaintiff, and other foreseeable users alike because they failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide.

192. Wyeth and Schwarz, NDA holders and Teva, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff because they failed to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

193. Wyeth and Schwarz, NDA holders and Teva, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff in that it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

194. Wyeth and Schwarz, NDA holders and PLIVA, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physician, Plaintiff and other foreseeable users alike, in that they failed to ensure Reglan, metoclopramide and metoclopramide HCl warnings to the medical community, including Plaintiff's physician and/or Plaintiff, were accurate and adequate.

195. Wyeth and Schwarz, NDA holders and Defendant PLIVA, ANDA holder, jointly breached their joint duty to the medical community, including Plaintiff's physicians, Plaintiff, and other foreseeable users alike because they failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

196. Wyeth and Schwarz, NDA holders and PLIVA, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff because it failed to review adverse drug experience information (hereinafter "ADE") and to report any significant data gleaned from that review regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide and metoclopramide HCl.

197. Wyeth and Schwarz, NDA holders and PLIVA, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff in that they failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

198. Wyeth and Schwarz, NDA holders and UDL Laboratories, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physician, Plaintiff and other foreseeable users alike, in that they failed to ensure Reglan, metoclopramide and

metoclopramide HCl warnings to the medical community, including Plaintiff's physician and/or Plaintiff, were accurate and adequate.

199. Wyeth and Schwarz, NDA holders and Defendant UDL Laboratories, ANDA holder, jointly breached their joint duty to the medical community, including Plaintiff's physicians, Plaintiff, and other foreseeable users alike because they failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

200. Wyeth and Schwarz, NDA holders and UDL Laboratories, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff because they failed to communicate material safety information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

201. Wyeth and Schwarz, NDA holders and UDL Laboratories, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff in that it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

202. Wyeth and Schwarz, NDA holders and UDL Laboratories, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physician, Plaintiff and other foreseeable users alike, in that they failed to ensure Reglan, metoclopramide and metoclopramide HCl warnings to the medical community, including Plaintiff's physician and/or Plaintiff, were accurate and adequate.

203. Wyeth and Schwarz, NDA holders and Defendant UDL Laboratories, ANDA holder, jointly breached their joint duty to the medical community, including Plaintiff's physicians, Plaintiff , and other foreseeable users alike because they failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

204. Wyeth and Schwarz, NDA holders and UDL Laboratories, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff because it failed to review adverse drug experience information (hereinafter "ADE") and to report any significant data gleaned from that review regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide and metoclopramide HCl to the medical community, Plaintiff's physician, Plaintiff and other foreseeable uses of Reglan/metoclopramide and metoclopramide HCl.

205. Wyeth and Schwarz, NDA holders and UDL Laboratories, ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff in that it failed to periodically review all medical literature and failed to communicate any significant data concerning neurological side effects, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users of Reglan, metoclopramide and metoclopramide HCl.

206. Wyeth and Schwarz, NDA holders and WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physician, Plaintiff and other foreseeable users alike, in that they failed to ensure Reglan, metoclopramide and metoclopramide HCl warnings to the medical community, including Plaintiff's physician and/or Plaintiff, were accurate and

adequate.

207. Wyeth and Schwarz, NDA holders and Defendant WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), ANDA holder, jointly breached their joint duty to the medical community, including Plaintiff's physicians, Plaintiff, and other foreseeable users alike because they failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

208. Wyeth and Schwarz, NDA holders and WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff because it failed to review and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

209. Wyeth and Schwarz, NDA holders and WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physicians and Plaintiff in that it failed to periodically review all medical literature and failed to report any significant data concerning neurological side effects, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl.

210. Wyeth and Schwarz, NDA holders and ACTAVIS ELIZABETH, LLC , ANDA holder, jointly breached their duty to the medical community, including Plaintiff's physician, Plaintiff and other foreseeable users alike, in that they failed to ensure Reglan,

metoclopramide and metoclopramide HCl warnings to the medical community, including Plaintiff's physician and/or Plaintiff, were accurate and adequate.

211. Wyeth and Schwarz, NDA holders and Defendant ACTAVIS ELIZABETH, LLC , ANDA holder, jointly breached their joint duty to the medical community, including Plaintiff's physicians, Plaintiff, and other foreseeable users alike because they failed to conduct post market safety surveillance of Reglan, metoclopramide, and/or metoclopramide HCl, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide.

212. Wyeth and Schwarz, NDA holders and ACTAVIS ELIZABETH, LLC, ANDA holder, jointly breached their duty to the medical community, including medical community, including Plaintiff's physician, Plaintiff and other foreseeable users alike because it and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by Reglan, metoclopramide or metoclopramide HCl, the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users.

213. Wyeth and Schwarz, NDA holders and ACTAVIS ELIZABETH, LLC, ANDA holder, jointly breached their duty to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users of Reglan/metoclopramide and metoclopramide HCl in that they failed to periodically review all medical literature and failed to communicate material safety data and information concerning neurological side effects, of this drug which effected the adequacy and/or accuracy of its warnings, efficacy, or safety of Reglan, metoclopramide, and/or metoclopramide HCl to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users of Reglan, metoclopramide and metoclopramide HCl.

214. ACTAVIS ELIZABETH, LLC, UDL Laboratories, WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), Teva, Pliva, Wyeth, and Schwarz jointly and severally, marketed, manufactured and distributed Reglan, metoclopramide and/or metoclopramide HCl and encouraged the long term use of these drugs, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

215. The drugs Reglan, metoclopramide and/or metoclopramide HCl were widely advertised by the Drug Company Defendants as a safe and effective treatment of diabetic gastroparesis, gastroesophageal reflux disease (GERD) and other gastrointestinal disorders.

216. At all times material hereto, Defendant Wyeth, individually and as successor-in-interest to A.H. Robins Company, as the NDA holder and RLD company, was aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathesia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism and failed to fulfill its obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, plaintiff's physician, plaintiff and other foreseeable users about the safety of the long term use of the drug.

217. At all times material hereto, Defendant Schwarz, as the NDA holder and RLD company, respectively, was aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathesia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism.

218. At all times material hereto, Defendant Wyeth, individually and as successor-in-interest to A.H. Robins Company, as the NDA holder and RLD company, knew or should have known that physicians were **not** aware of or did not fully appreciate the seriousness of the

risks associated with use of Reglan/metoclopramide and that consequently there was a widespread tendency for physicians to prescribe Reglan/metoclopramide for long-term use.

219. At all times material hereto, Defendant Schwarz, as the NDA holder/RLD Company and purchaser of the innovator's Reglan, metoclopramide and metoclopramide HCl interest, knew or should have known that physicians were **not** aware of or did not fully appreciate the seriousness of the risks associated with use of Reglan/metoclopramide and that consequently there was a widespread tendency for physicians to prescribe Reglan/metoclopramide for long-term use.

220. The DRUG COMPANY DEFENDANTS knew or should have known that the package insert and the Physician Desk Reference monograph for Reglan/metoclopramide did not adequately inform physicians about the risks associated with Reglan/metoclopramide, particularly for patients whose bodies do not metabolize Reglan, metoclopramide, and/or metoclopramide HCl effectively, yet said Defendants failed to communicate said information to the medical community, Plaintiff's physicians, Plaintiff or other foreseeable users alike, and in doing so, mislead the medical community, physicians, plaintiff's physician, plaintiff and other foreseeable users about the safety of the long term use of this drug.

221. Schwarz as the NDA holder and/or Referenced Listed Drug holder(s), failed to report safety information regarding severe side effects of Reglan, metoclopramide, and metoclopramide HCl, it knew or should have known from a review of information it was privy to by virtue of its indemnification agreement with Wyeth, from a review of data from clinical studies that were not publicly available, through its review of domestic and international medical literature concerning Reglan/ metoclopramide and through ongoing litigation involving Reglan, metoclopramide and metoclopramide HCl and in doing so,

mislead the medical community, physicians, plaintiff's physician, plaintiff and other foreseeable users about the safety of the long term use of the drug.

222. Defendant Wyeth knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

223. Wyeth failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

224. Defendant Schwarz knew or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

225. Schwarz failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

226. Defendant PLIVA, as an ANDA holder, knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

227. PLIVA failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

228. Defendant Teva, as an ANDA holder, knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially

understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

229. Teva failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

230. Defendant UDL Laboratories, as an ANDA holder, knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

231. UDL Laboratories failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

232. Defendant ACTAVIS ELIZABETH, LLC, as an ANDA holder, knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

233. ACTAVIS ELIZABETH, LLC failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

234. Defendant WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle), as an ANDA holder, knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

235. WYETH, by and through ESI Lederle (a/k/a ESI, a/k/a Lederle) failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

236. Defendant PUREPAC, as an ANDA holder, knew, or should have known through the exercise of reasonable care, that the package insert for Reglan/metoclopramide substantially understated the prevalence of acute and long term side effects of Reglan/metoclopramide.

237. Purepac failed to use reasonable care to modify the package insert to adequately warn physicians about the true risks of both short term use and long term use, even after several injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

238. Defendants failed and continue to fail to use reasonable care to modify the package insert for Reglan, metoclopramide and metoclopramide HCl, to adequately and accurately warn the medical community, Plaintiff's physician, and plaintiff about the true risks of both short term use and long term use, even after numerous injured patients filed lawsuits alleging inadequate warnings and produced competent expert testimony supporting their allegations.

239. Defendant Wyeth and its predecessors in interest had actual knowledge, through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide for long term use that was not safe for patients.

240. Defendants Schwarz and its predecessors in interest had actual knowledge, through their own studies and studies by independent investigators, that doctors frequently prescribed Reglan/metoclopramide for long term use that was not safe for patients.

241. Defendant Wyeth and its predecessors in interest had actual knowledge, through their own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan/metoclopramide received it on doctor's prescriptions for 12 months or longer, rather than 12 weeks or less.

242. Defendant Wyeth also had actual knowledge, through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide in patients who receive the drug for 12 weeks or longer is approximately 100 times greater than disclosed in Wyeth's package insert for Reglan and the Physicians Desk Reference monograph for Reglan brand metoclopramide and failed to correct their monograph and/or disclose that knowledge to the medical community, physicians, plaintiff's physician, plaintiff and other foreseeable users.

243. Defendant Wyeth knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize Reglan/metoclopramide and that as a foreseeable consequence of their inability to effectively metabolize Reglan/metoclopramide, those patients have a greater risk of developing serious and permanent injuries, which it failed to disclose this material safety information to the medical community and failed to adequately disclose to the generic pharmaceutical industry.

244. Defendant Wyeth willfully and in wanton disregard of the rights of Plaintiff and other persons in Plaintiff's class, failed to disclose and communicate material safety information regarding the risks of this drug to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed Reglan/metoclopramide by a physician who was not aware of this information.

245. Defendant Wyeth knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize Reglan/metoclopramide and that as a foreseeable consequence of their inability to effectively metabolize Reglan/metoclopramide, those patients have a greater risk of developing serious and permanent injuries, but failed to communicate this material safety information to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed Reglan/metoclopramide by a physician who was not aware of this information.

246. Defendant Schwarz in interest had actual knowledge, through their own studies and studies by independent investigators, that nearly one-third of all patients who used Reglan/metoclopramide received it on doctor's prescriptions for 12 months or longer, rather than 12 weeks or less.

247. Defendant Schwarz also had actual knowledge, through research by independent investigators, that the risk of tardive dyskinesia and other extrapyramidal side effects of Reglan/metoclopramide in patients who receive the drug for 12 weeks or longer is approximately 100 times greater than disclosed in Wyeth's package insert for Reglan and the Physicians Desk Reference monograph for Reglan brand metoclopramide and failed to correct their monograph and/or disclose that knowledge to the medical community, physicians, plaintiff's physician, plaintiff and other foreseeable users.

248. Defendant Schwarz knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize Reglan/metoclopramide and that as a foreseeable consequence of their inability to effectively metabolize Reglan/metoclopramide, those patients have a greater risk of developing serious and permanent injuries, but it failed to communicate this material

safety information regarding the risks to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed Reglan/metoclopramide by a physician who was not aware of this information.

249. Defendant Schwarz willfully and in wanton disregard of the rights of Plaintiff and other persons in Plaintiff's class, failed to communicate the aforesaid information to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed Reglan/metoclopramide by a physician who was not aware of this information.

250. Defendant Schwarz knew, or through the exercise of reasonable care should have known, that many patients who use Reglan/metoclopramide are not able to effectively metabolize Reglan/metoclopramide and that as a foreseeable consequence of their inability to effectively metabolize Reglan/metoclopramide, those patients have a greater risk of developing serious and permanent injuries, but failed to communicate this material safety information to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed Reglan/metoclopramide by a physician who was not aware of this information.

251. Defendant Schwarz willfully and in wanton disregard of the rights of Plaintiff and other persons in Plaintiff's class, failed to communicate the material safety information to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users, knowing that such failure would result in serious injury to patients who were prescribed Reglan/metoclopramide by a physician who was not aware of this information.

252. Defendant Schwarz failed to disclose *any* information regarding the adequacy and accuracy of the warnings for Reglan, metoclopramide and metoclopramide HCl and/or

safety or efficacy of the drug with the full knowledge that such failure, would result in serious injury to patients who were prescribed Reglan/metoclopramide by a physician who was not aware of this information, and thereby acted in willful and wanton disregard of the rights of persons in the Plaintiff 's class, and this conduct caused serious injury to the Plaintiff.

253. Wyeth misrepresented the safety of Reglan, metoclopramide and metoclopramide HCl, and withheld warnings of the known side effects the drug as commonly prescribed by physicians.[6]

254. Defendant Wyeth, individually and as successor-in-interest to A.H. Robins Company, was aware of the serious side effects caused by Reglan/metoclopramide including, but not limited to, central nervous system disorders, depression with suicidal ideation, akathesia, tardive dyskinesia, tardive dystonia, visual disturbances and interference with drug metabolism, yet breached its duty to the medical community, Plaintiff's physician, Plaintiff and other like foreseeable users by failing to communicate such side effects, to the medical community, Plaintiff's physician, Plaintiff and other foreseeable users.

255. Wyeth breached its duty, as the NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, by misrepresenting the safety and efficacy of the drug, with the intent to defraud and deceive physicians, including Plaintiff's physician, and through them to defraud and deceive Plaintiff, with the intent to induce practitioners to use Reglan/metoclopramide as pharmaceutical treatment for diabetic gastroparesis for a period of time that far exceeded the FDA's approved indicated duration of use.

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[6]*See* 21 C.F.R. § 201.128.

256. Wyeth as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, knew or should have known that a patient was at a significantly increased risk of developing a severe and permanent neurological movement disorder from the long term ingestion of Reglan, metoclopramide and metoclopramide HCl, given the published medical literature.

257. As set forth above, Wyeth as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, and its predecessors falsely and fraudulently represented to physicians, Plaintiff's physicians, and to foreseeable users, including Plaintiff, that the drug was safe to use in the treatment of diabetic gastropaeries and that permanent neurological side effects were comparatively rare.

258. As set forth above, Wyeth as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, and its predecessors falsely and fraudulently failed to disclose to the medical community, physicians, plaintiff's physician, plaintiff and other foreseeable users that the long term use of the drug at issue, exposed diabetics, including Plaintiff, to a greater risk of extrapyramidal side effects than the non-diabetic user.

259. All Drug Company defendants negligently and intentionally failed to disclose to the medical community, physician, plaintiff's physician, plaintiff and other foreseeable users that patients with diabetes who were exposed to metoclopramide were more likely to develop tardive dyskinesia than metoclopramide-treated non-diabetics.

260. Wyeth as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors did not disclose or warn physicians about the actual prevalence of known side effects of Reglan/metoclopramide, particularly when Reglan/metoclopramide is used on a ***long term basis***, as marketed by Wyeth, or when used in patients who are poor metabolizers of metoclopramide, all of

which were foreseeable.

261. At the time Wyeth as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors made the above described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

262. Schwarz breached its duty as the NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, by misrepresenting the safety and efficacy of the drug, with the intent to defraud and deceive physicians, including Plaintiff's physician, and through them to defraud and deceive Plaintiff, with the intent to induce practitioners to use Reglan/metoclopramide as pharmaceutical treatment for diabetic gastropaeries for a period of time that far exceeded the FDA's approved indicated duration of use.

263. Schwarz as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, knew or should have known that a patient was at a significantly increased risk of developing a severe and permanent neurological movement disorder from the long term ingestion of Reglan, metoclopramide and metoclopramide HCl, given the published medical literature.

264. As set forth above, Schwarz as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, and its predecessors falsely and fraudulently represented to physicians, Plaintiff's physicians, and to foreseeable users, including Plaintiff, that the drug was safe to use in the treatment of diabetic gastropaeries and that permanent neurological side effects were comparatively rare. These representations were, in fact, false. The true facts were that Reglan/metoclopramide was not safe for that purpose and was, in fact, dangerous to the health and body of Plaintiff.

265. Schwarz as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors did not disclose or warn physicians about the actual prevalence of known side effects of Reglan/metoclopramide, particularly when Reglan/metoclopramide is used on a ***long term basis***, as marketed by Schwarz, or when used in patients who are poor metabolizers of metoclopramide, all of which were foreseeable.

266. At the time Schwarz, as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors made the above described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

267. In reliance upon the representations of Schwarz and Wyeth as the NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors Plaintiff's physicians were induced to and did prescribe Plaintiff Reglan, metoclopramide and/or metoclopramide HCl.

268. If Plaintiff's' physicians had known the actual risk posed to Plaintiff, particularly the increased risk posed to Plaintiff, as a diabetics, he/she would not have prescribed Reglan to Plaintiff.

269. Plaintiff justifiably relied on Plaintiff's physicians, and Plaintiff reasonably relied upon the representations of Wyeth and Schwarz, as the NDA holder and/or Referenced Listed Drug Company/ innovator of Reglan.

270. Plaintiff's physicians reasonably believed as prudent physicians would that Defendants Wyeth and Schwarz would fully, truthfully and accurately disclose the risks of side effects associated with Reglan, metoclopramide and/or metoclopramide HCl in their drug label, *Physicians Desk Reference* and other literature and data.

271. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Wyeth's breach of its duty as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl and its predecessors, dissemination to physicians of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential side effects of Reglan, metoclopramide and/or metoclopramide HCl.

272. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Schwarz's breach of its duty as an NDA holder and/or Referenced Listed Drug Company for Reglan, metoclopramide and metoclopramide HCl, dissemination to physicians of inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the potential side effects of Reglan, metoclopramide and/or metoclopramide HCl.

273. In doing the acts alleged in this Complaint, Wyeth and its predecessors acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages to deter Wyeth and others from engaging in similar conduct in the future.

274. Wyeth's wrongful conduct was done with the advance knowledge, authorization, or ratification of an officer, director, or managing agent of each of Wyeth and its predecessors.

275. In doing the acts alleged in this Complaint, Schwarz acted with oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages to deter Schwarz and others from engaging in similar conduct in the future.

276. Schwarz's wrongful conduct was done with the advance knowledge, authorization, or ratification of an officer, director, or managing agent of each of Schwarz and its predecessors.